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EXAMINER

ZALUKAEVA, TATYANA

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/917,971  
Filing Date: July 30, 2001  
Appellant(s): MENTAK, KHALID

**MAILED**

JUL 14 2004

**GROUP 1700**

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Jeffrey D. Peterson  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed April 26, 2004.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is deficient because on page 3, bottom paragraph of Brief, Appellant provides the definition of a "high water content hydrogel forming *monomer*", (emphasis added) as "...materials which are hard or rigid when dry, and absorb a large amount of water (e.g. up to 20%-70% by weight) when hydrated, and lowers the refractive index of the material" and refers to page 1, line 27.

However, lines 27-33 on page 1 define NOT a monomer, but a MATERIAL, which is a polymer formed from several monomers. This is an important issue in understanding the summary of invention, since the entire Appellants argument is based on the alleged difference between their "third monomer" and the prior art hydrogel forming monomer.

**(6) Issues**

The appellant's statement of the issues in the brief is correct.

**(7) Grouping of Claims**

Appellant's brief includes a statement that claims 33, 37 and 34-36 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

**(8) Claims Appealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

4,731,079	Stoy	03/1988
5,453,530	Byerley et al	09/1995
4,962,170	Chromecek et al	10/1990

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 33, 34 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Stoy (U.S. 4,731,079). This rejection is set forth in a prior Office Action, mailed on May 27, 2003.

Stoy discloses a method of manufacturing an intraocular lens (IOL), the embodiment presented in Example 2 in col. 14 clearly reads on the limitations of the instant claims 33, 34 and 37.

Thus, 85 grams of benzyl Acrylate, (*first monomer of the instant claim 33*) 15 grams of styrene (*second monomer of the instant claim 33*) and 0.35 grams of tetraethyleneglycol-bis-methacrylate (*third monomer of the instant claim 33*) were polymerized under nitrogen by means of 0.075 grams of benzoylperoxide (lines 50-56 of col. 14).

With regard to the third monomer of the instant claim 33, the teaching of Stoy is that "A particularly preferred co-polymer is a combination of **at least** two co-monomers composed of the following: a first monomer component which when polymerized forms a hydrophobic polymer with a  $T_g$  higher than  $37^{\circ}\text{C}$ , and, a second monomer component which when polymerized forms a hydrophilic polymer or hydrogel " (col. 8, lines 23-29, especially, lines 28, 29).

Refractive index of the polymer was 1.570.  $T_g$  ( $T_g$ ) is  $25.5^{\circ}\text{C}$  (lines 57-59 of col. 14). (*This anticipates the refractive index of the instantly claimed polymer*).

The copolymer was lathed into the shape of a biconvex lens (line 60 of col. 14). This anticipates step (b) of the instant claim 33 .

The lens was then inserted in a tube made from a roll of stainless steel, 0.5 mm in thickness. The roll and the lens were immersed in nearly boiling water for several seconds. Then the roll containing the deformed lens was immersed in a jar of saline solution (col. 15, lines 1-4) . This is a **hydrating step ( c )** of the instant claim 33. The deformed (or foldable) lens was readily insertable through a facoemulsification incision by means of forceps or another suitable instrument. (see Example II in columns 14 and 15). According to Stoy, when the finished lens is placed in an isotonic saline solution for

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24 hours at ambient temperature, from the lens' weight increase it was found that its equilibrium water content was about 10% by weight (column 16, lines 10-15). This meets the limitations of claim 33 in terms of equilibrium water content. The polymers of Stoy are lathed and polished (col.8, lines 36, 37). This meets the limitations of the instant claim 37

Claim 35 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stoy.

The property of central thickness is not elucidated by Stoy. However, there are two aspects Examiner would like to address here. The first one is that since the polymers of Stoy are essentially the same as instantly claimed, and they are made via essentially the same method as instantly claimed, therefore the properties even not taught, will be inherently the same as a per In re Fitzgerald (205 USPQ 594). (CAFC) The onus to show that this, in fact, is not the case was shifted to Appellant.

The second consideration is that Stoy teaches that at 31.5 Diopters the central thickness is 0.73 mm. If the proportion works in this case (taking into account the identity of the claimed and disclosed products) than the thickness at 20 Diopters should be very close the claimed range  $(20 \times 0.73 / 31.5) = 0.46$  mm.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stoy. Stoy does not specify the sequence of hydrating steps.

However, Stoy clearly suggest plasticizing with water or saline solution, and suggests different modes of such plastification. Considering the absence of criticality of the particular mode of hydration, and the generic teaching of Stoy with regard to hydration, a person skilled in the art would have found it obvious to utilize any sequence of steps including one of the instant claims with the reasonable expectation of success. *In re Burhans* 69 USPQ 330 (CCPA 1946): Selection of any order of performing process steps is prima facie obvious in the absence of new and unexpected results

**(11) Response to Argument**

Appellant's arguments in Brief filed April 26, 2004 have been fully considered but they are not persuasive.

With regard to claim 33, Appellant's major argument resides in contention that the Stoy reference fails to disclose a third monomeric component which comprises a "high water content hydrogel-forming monomer", as per instant claim 33.

Appellant further argues that " This limitation specifies that the third monomeric component alone, when polymerized, would form a hydrogel. The specification of the application discloses that high water content hydrogel forming monomers are: Materials [which] are hard or rigid when dry, and absorb a large amount of water (e.g. up to 20%-70% by weight) when hydrated, which lowers the refractive index

of the material" and Appellant refers to page 1, line 27 of the specification.

Examiner absolutely disagrees with such interpretation of "third monomer" and with Appellant's argument for the following reasons:

- The passage from specification recited by Appellants (page 1, line 27 and other places in the spec) relates NOT to the monomers, but to the copolymers formed by these monomers. Nowhere in the instant specification the information and/or guidance is found that the third monomer when polymerized ALONE would form a hydrogel. To the contrary the instant specification provides support to the fact the "third monomer" is one that imparts the hydrogel properties to the copolymers when polymerized with other comonomers. This is also the Examiner's interpretation of the third monomer. And this is totally in accordance with Stoy's teaching in col. 8, lines 27-29 "...second monomer component which when polymerized forms a hydrophilic polymer or hydrogel"

Next Appellant's argument is that tetraethylene glycol –bis-methacrylate (TEGDMA) of Stoy is not a hydrogel forming monomer of the instant claim 33 (see paragraph bridging pages 7 and 8 of Brief). Appellant further argues that the references that were used by the Examiner to rebut Appellants' allegations that the TEGDMA is not a "third monomer" have not been used in a statutory rejection.



In response to this, in the Final Office Action on the merits, it was shown that references (U.S. 5,453,530, col. 9, lines 32-40 and U.S. 4,962,170, col. 3, lines 44-46) were only used as a documentary evidence to rebut Applicants' argument that TEGDMA is NOT a hydrogel forming monomer, and to provide documentary evidence that that tetraethylene glycol –bis-methacrylate IS a hydrogel forming high water content monomer. It is noted that the cited references **are in no way used for new grounds of rejection, but to rebut Applicants' arguments with documentary evidence.**

The crux of further Appellants' argument is that the documentary evidence submitted by the Examiner as (U.S. 5,453,530, col. 9, lines 32-40 and U.S. 4,962,170, col. 3, lines 44-46) does not show that TEGDMA when polymerized alone is a hydrogel forming monomer. In response to this it is noted that NEITHER the instant claims, NOR the instant specification shows expressly or implicitly that the "third monomer" if polymerized ALONE would have formed the hydrogel polymer. Therefore, both the express teaching of Stoy (col. 8, lines 27-29) and the documentary evidence submitted by the Examiner provide that the "third monomer" of the instant claim 33 is anticipated by the TEGDMA monomer of Stoy.

Appellants further Arguments are based on the Declaration under 37 CFR 1.132 submitted on November 24, 2003 after Final Office Action on the merits.

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The Declaration under 37 CFR 1.132 filed November 24, 2003 was insufficient to overcome the rejection of claims 33-37 based upon Stoy as set forth in the Advisory Action mailed on January 22, 2004 because:

- a) the entire declaration is based on the theoretical speculation that the TEGDMA monomer of Stoy is not a hydrogel forming monomer, as recited in the instant claims;
- b) Dr, Mentak in his Declaration argues that the two references cited by the Examiner as an EVIDENCE that the TEGDMA monomer serves a hydrogel forming monomer, do not in fact provide such evidence, because they fulfill different functions in both cited references. Further, Declaration elaborates on the fact that the "third monomer" of the instant claims forms hydrogel when polymerizes ALONE;

This is not found persuasive for at least three reasons:

- a) It has been already addressed that the instant specification and claims do not provide express or implicit definition of a hydrogel forming monomer, as alleged by Appellant;
- b) the reference to Stoy himself provides the preferred embodiment with the presence of a hydrogel forming monomer (col. 8, lines 27-29);
- c) Appellant is reminded that the identity required for anticipation is between the claimed subject matter and the subject matter disclosed by the reference, identity does not require the reference to disclose the same subject matter as described in the specification. See Kalman vs. Kimberly Clark Corp, 218 USPQ 781 (Fed. Cir.1983). It is further noted that Examiner has the duty to police the claim language by giving it the broadest possible interpretation", Springs Window Fashions LP v. Novo Industries L.P.,

65, USPQ 2d 1826, 1830 (Fed. Cir. 2003). Furthermore, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art...". In re Morris, 44 USPQ 2d 1023,1027 (Fed. Cir, 1997). In light of the above the **hydrogel forming or high water content monomer**, as broadly claimed in the instant claim 33) is given its broadest and commonest interpretation, also found in Appellants' specification, and the reference to Byerley, for instance, the interpretation/meaning of the third monomer, of Stoy: " For example, when a crosslinked polymer **capable of forming a hydrogel is desired** the comonomer can be one or more of ....tetratethylene glycol) diacrylate and **tetratethylene glycol) dimethacrylate**". (col.9, lines 32-40).

With regard to claim 34, Appellants' argument resides in contention that the Stoy reference fails to disclose the limitation that "...the rigid intraocular lens and the foldable hydrated intraocular lens differ in volume by less than about 10%". Appellant argues that the Examiner has made the assertion on the weight percent increase due to the water content not to the volume.

In response to this argument, Appellants' attention is drawn to column 16, lines 10-15 of Stoy: "...when the finished lens is placed in an isotonic saline solution for 24 hours at ambient temperature, from the lens' weight increase it was found that its equilibrium water content **was about 10% by weight**" **Since the 10% increase by**

**weight is due to WATER and water density is 1g/cm<sup>3</sup>, then the change in vilume will be the same as the change of weight due to the water content.**

Appellant further argues that the statutory rejection was not made by using references to Byerley and Chromecek, and therefore the rejection under Stoy's reference should be withdrawn. It has already been addressed that the Stoy reference by itself is absolutely sufficient for anticipation rejection, and that two other references were attracted by the Examiner solely for the purpose to rebut Applicants argument by the documentary evidence, but in no way were used for the rejection.

Appellants' argument with regard to claim 35 resides in contention that Stoy discloses a lens of 31.5 diopters with the thickness of 0.73 mm, not the thickness and diopters of the instant claim 35. Appellants further argue that the decrease in thickness would have decreased the refractive index. This is not found persuasive, because Appellant has not presented a valid side-by-side comparison between their refractive index and that of Stoy wherein the only difference is the thickness of the lens. **In re Dunn**, 349 F. 2d 433, 146 USPQ 489 (CCPA 1965).

Furthermore, Appellant has not rebutted the presumption of In re Fitzgerald, set forth by the Examiner in the Final Office Action, by any experimental evidence. With regard to rejection of claim 36 under 35 USC 103 (a) as being unpatentable over Stoy, Appellant's argument resides in contention that the steps as claimed "...are important to help to obtain intraocular lens with the desired properties... equilibrium

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water concentration of 10weight %, a refractive index greater than about 1.55..." (Claim 36 depends on claim 33, therefore the properties of optic size, thickness, etc. are not present in claim 36.)

It is first noted that the properties listed here by Appellant ARE ACHIEVED by Stoy, as discussed above. And second, the Appellant failed to show the criticality of the steps, as claimed.

For the above reasons, it is believed that the rejections should be sustained.

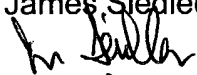
Respectfully submitted,

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July 8, 2004

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